DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2015

Hospira, Inc.
Ms. Anju Kurian
Associate, Regulatory Affairs
D- 0393 Bldg. H3
375 N. Field Drive
Lake Forest, Illinois 60045

Re: K143015
Trade/Device Name: Hospira Primary Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Sets
Regulatory Class: II
Product Code: FPA
Dated: January 23, 2015
Received: January 26, 2015

Dear Ms. Kurian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K143015

Device Name: Hospira Primary Set

Indications for Use: Hospira Primary sets are indicated for the delivery of fluids from a container to a patient's vascular system.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5: 510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92 for Hospira Primary Sets.

Submitter Information	
Name	Hospira, Incorporated
Address	D-393, Bldg. H3 375 North Field Drive Lake Forest, IL. 60045
Phone number	(224) 212-6141
Fax number	(224) 212-5401
Establishment Registration Number	3005579246 (Owner/Operator #9063339)
Name of contact person	Anju Kurian, Associate, Global Regulatory Affairs
Date prepared	10/17/2014
Name of device	
Trade or proprietary name	Hospira Primary Sets
Common or usual name	I.V Administration Sets
Classification name	Intravascular Administration Set, 21 CFR 880.5440, Class II
Product Code(s)	FPA
Legally marketed device(s) to which equivalence is claimed	Hospira Primary Sets – K142367
Reason for 510(k) submission	The changes addressed in this submission include: • Modification to Secure Lock Male Luer
Device description	The Hospira Primary Sets with Secure Lock are intended for use as gravity sets. Primary Sets are comprised of a variety of components, at a minimum including a male luer adapter with spin collar, a piercing pin assembly, a cap on each adapter, injection site assembly, dial-a-flo assembly and tubing . In addition to these components, a set may contain one or more of the following components: flow control device, drip chamber assembly and air inlet. Hospira Primary sets are intended for the delivery of fluids from a container to a patient's vascular system. Hospira infusion sets are disposable devices for single patient use.
Intended Use of Device	A Hospira Primary set is intended for the delivery of fluids from a container to a patient's vascular system.

Summary of the technological characteristics of the device compared to the predicate device		
Characteristic	**Predicate 510 (k) : K142367**	**Proposed Device**
Indications for Use	Hospira Primary Sets are indicated for the delivery of fluids from a container to a patient's vascular system.	Hospira Primary Sets are indicated for the delivery of fluids from a container to a patient's vascular system.
Design and Materials of Construction	The materials of construction for the proposed device are exactly the same as the materials for the predicate product	The design and materials of construction remain the same as the predicate product.
Summary of non-clinical tests for determination of substantial equivalence	All materials of construction for Hospira Primary Sets meet the applicable material test requirements for ISO 10993.	All materials of construction for Hospira Primary Sets meet the applicable material test requirements for ISO 10993.
Summary of Performance Testing	Performance testing was conducted to ensure the device performs as intended in accordance with applicable standards. All testing is acceptable. The product Sterility Assurance Level is 10^{-6}.	New performance data has been generated to ensure the device performs as intended in accordance with ISO 594-1, ISO 594-2 and ISO 8536-4. All testing is acceptable. The product Sterility Assurance Level is 10^{-6}.

Conclusion

Hospira Primary Sets meet the functional claims and intended use as described in the product labeling. The safety and effectiveness are substantially equivalent to Hospira Primary Sets cleared under K142367.